**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF ILLINOIS**

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| PEOPLE OF THE STATE OF ILLINOIS and ST. CLAIR COUNTY, ILLINOIS,<br><br>Plaintiffs,<br><br>v.<br><br>PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; ABBOTT LABORATORIES; and ABBOTT LABORATORIES, INC.,<br><br>Defendants. | Case No. 17-cv-00616<br><br>Honorable Michael J. Reagan |

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS PURDUE PHARMA L.P., PURDUE PHARMA INC., AND THE PURDUE FREDERICK COMPANY INC.'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM**

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Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc. (together, "Purdue") respectfully submit this memorandum of law in support of their motion to dismiss the Complaint of Plaintiffs St. Clair County (the "County") and the People of the State of Illinois.

## I. INTRODUCTION

The Food and Drug Administration ("FDA"), National Institutes of Health, the Center for Disease Control and Prevention, as well as numerous physicians groups and public health organizations all recognize that "[c]hronic pain is a serious and growing health problem: it 'affects millions of Americans; contributes greatly to national rates of morbidity, mortality, and disability; and is rising in prevalence.'"[1] Purdue's opioid medications serve a critical public health role. As FDA has determined, "[w]hen prescribed and used properly, opioids can effectively manage pain and alleviate suffering—clearly a public health priority." Ex. 1 at 2.

The key, however, is proper use. It has long been known that "[o]pioids also have grave risks, the most well-known of which include addiction, overdose, even death." *Id.* As FDA has recognized, "the labeling for these products contains prominent warnings about these risks. Moreover, the boxed warning states that all patients should be 'routinely monitor[ed] . . . for signs of misuse, abuse, and addiction.'" *Id.*

Though the majority of medical and public health organizations—including FDA—recognize that opioid medications can be appropriate for treating long term chronic pain, one organization, Physicians for Responsible Opioid Prescriptions ("PROP"), filed a citizen petition with FDA seeking more restrictive limits on opioid use. PROP questioned the effectiveness of

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[1] *See* Sept. 10, 2013 Letter from FDA to PROP ("FDA Response") at 2 & nn.4-6, attached hereto as Ex. 1; July 25, 2012 Letter from PROP to FDA ("PROP Petition"), attached hereto as Ex. 2. Because the Complaint refers to the PROP Petition and the FDA Response, *see, e.g.* Compl. ¶ 55, they are incorporated by reference in the Complaint, and the Court may consider them. *See, e.g.*, *Tierney v. Vahle*, 304 F.3d 734, 738 (7th Cir. 2002); *Wright v. Associated Ins. Cos.*, 29 F.3d 1244, 1248 (7th Cir. 1994).

opioid medication for long term use and sought to limit use in non-cancer patients to 90 days. FDA rejected these proposed restrictions, explaining: "After a review of the literature cited in the Petition, and an assessment of other relevant information discussed below, FDA has determined that limiting the duration of use of opioid therapy to 90 days is not supportable." Ex. 1 at 14.

Despite FDA's conclusion that opioid medications should continue to be available for the treatment of chronic pain, Plaintiffs now bring this lawsuit alleging that "the use of opioids to treat chronic pain is neither 'in accordance with generally accepted standards of medical practice' nor 'clinically appropriate.'" Compl. ¶ 351. Based on this theory, the County seeks a refund for payments made for "chronic opioid therapy" through its self-insured health care plans and its workers' compensation program. *See, e.g.*, *id.* ¶ 470. The Complaint is facially deficient and subject to dismissal on multiple grounds.

*First*, the State of Illinois is not a proper party to this action. The St. Clair State's Attorney does not have authority to bring this action on behalf of the State of Illinois given a prior consent judgment entered into between Purdue and the Illinois Attorney General.

*Second*, the Complaint fails to set forth, let alone with the particularity required by Federal Rule of Civil Procedure 9(b), facts sufficient to state a cause of action. The Complaint contains no allegations identifying a single St. Clair County prescriber who allegedly: (i) received any misrepresentation from Purdue, (ii) was deceived in any manner regarding the risks involved with Purdue opioid medications, or (iii) who wrote any allegedly improper prescription for a Purdue opioid medication as a result of a misrepresentation, let alone a prescription reimbursed by the County. This fundamental failure is unsurprising given that Plaintiffs appear to have copied virtually all of the allegations from a complaint filed by the City of Chicago against Purdue and other opioid manufacturers in a Northern District of Illinois action.[2] In that

[2] *See* Third Am. Compl., *City of Chi.*, Dkt. No. 478 (N.D. Ill. Oct. 25, 2016).

case, the court has twice dismissed the fraud-based claims against Purdue because the City "failed to adequately allege that the prescribers who received defendants' deceptive publications are the same prescribers who wrote prescriptions for defendants' drugs that the City paid." *City of Chi. v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058, 1082 (N.D. Ill. 2016). The same result is warranted here.[3]

*Finally*, each count suffers from numerous additional claim-specific deficiencies requiring dismissal, not the least of which is failure to identify any purportedly false claims submitted to the County for reimbursement.

## II. LEGAL STANDARD

All of Plaintiffs' claims are based on allegations that Purdue fraudulently misrepresented the safety and efficacy of opioids to St. Clair and Illinois prescribers. Because all of the claims "sound[] in fraud," all must meet the plausibility standard of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and the particularity standard of Rule 9(b). *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007).[4] To satisfy *Twombly*, the allegations must transcend the "speculative" and "conceivable," and "state a claim to relief that is plausible on its face." 550 U.S. at 555, 570. To satisfy Rule 9(b), the Complaint must set forth the "who, what, when, where, and how" of the alleged fraud. *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990).

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[3] In *City of Chicago*, the court permitted claims to be advanced under two municipal ordinances that were held not to require causation or actual injury. 211 F. Supp. 3d at 1073-74, 1076. Such claims are not at issue here, nor may the County advance an enforcement action under the Illinois Consumer Fraud Act ("ICFA").

[4] *See also Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co.*, 631 F.3d 436, 446-47 (7th Cir. 2011) (consumer fraud claim subject to Rule 9(b)); *Camasta v. Jos. A Bank Clothiers, Inc.*, 2013 WL 474509, at *2 (N.D. Ill. Feb. 7, 2013) (same for UDTPA); *Cont'l Cas. Co. v. Mohatare*, 2012 WL 4830419, at *2 (N.D. Ill. Oct. 10, 2012) (same for insurance fraud); *Borsellino*, 477 F.3d at 507-08 (same for civil conspiracy); *Cincinnati Life Ins. Co. v. Beyrer*, 722 F.3d 939, 950 (7th Cir. 2013) (same for unjust enrichment predicated on fraud).

## III. ARGUMENT

### A. The State is Not a Proper Party to This Action.

The St. Clair State's Attorney cannot assert claims for putative violations of ICFA or the Uniform Defective Trade Practice Act ("UDTPA") (Counts 1 and 2) on behalf of the "People of the State of Illinois,"[5] because such claims are subject to a Consent Judgment entered into by the Illinois Attorney General—the "legal officer of the State," Ill. Const. 1970, art. V, § 15—on behalf of the State of Illinois in *The People of the State of Illinois v. Purdue Pharma, L.P.*, No. 07-CH-356 (Ill. Cir. Ct. 2007) ("Consent Judgment"), attached hereto as Ex. 3.[6] That Consent Judgment released claims the St. Clair State's Attorney now seeks to bring and also imposed procedural conditions precedent on the Attorney General for future actions by the State relating to Purdue's promotion of OxyContin. The St. Clair County State's Attorney does not have authority to act on behalf of the State under the Consent Judgment, nor have those conditions precedent been met. A county State's Attorney cannot advance claims on behalf of the State in derogation of a Consent Judgment entered by the Attorney General on behalf of the "People of the State of Illinois." *See People ex rel. Devine v. Time Consumer Mktg., Inc.*, 782 N.E.2d 761, 767-68 (Ill. App. Ct. 2002) (State's Attorney barred from bringing ICFA claims on behalf of State where Illinois Attorney General entered into a settlement); *accord Cty. of Cook v. Philip Morris, Inc.*, 817 N.E.2d 1039, 1041-42 (Ill. App. Ct. 2004) (noting dismissal of Complaint brought by State's Attorney on behalf of State in the wake of settlement agreement entered by the Illinois Attorney General).

As set forth more fully in Purdue's Notice of Removal (Dkt. No. 1) and Purdue's Memorandum of Law in Opposition to Plaintiffs' Motion to Remand (Dkt. No. 30), the Consent

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[5] Counts 3 through 5 are brought only on behalf of the County.

[6] The Court can take judicial notice of the Consent Judgment, a matter of public record, on a motion to dismiss. *See, e.g., Estate of Brown v. Arc Music Grp.*, 523 F. App'x 407, 410 (7th Cir. 2013); *Henson v. Credit Servs.*, 29 F.3d 280, 284 (7th Cir. 1994).

Judgment entered by the Attorney General on behalf of the State released all claims that could have brought on behalf of the State, prior to May 8, 2007, under the State Consumer Protection Laws relating to the promotional or marketing practices of OxyContin:

> [T]he State releases and forever discharges, to the fullest extent permitted by law, Purdue and its past and present . . . co-promoters . . . (collectively, the "Releasees"), of and from any and all civil causes of action, claims, damages, costs, attorney's fees, or penalties that the Attorney General could have asserted against the Releasees under the State Consumer Protection Law by reason of any conduct that has occurred at any time up to and including the Effective Date of this Judgment relating to or based upon the Subject Matter of this Judgment.

Ex. 3 at ¶ 35.

Many of the allegations in the Complaint predate the entry of the Consent Judgment, *e.g.*, Compl. ¶¶ 74, 131, 147-49, 156, 208, 239, 244, 256, 312, 324-29, and are therefore released.[7] Additionally, the allegations that post-date the entry of the Consent Judgment cannot be maintained because the St. Clair State's Attorney does not have authority regarding the notice and cure provisions of the Consent Judgment, and no such conditions precedent have been met. The St. Clair State's Attorney cannot circumvent these binding terms of the Consent Judgment entered between the Attorney General and Purdue. Nor can the State evade its obligations under the Consent Judgment simply by using a different lawyer who purports to act in the name of the

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[7] Plaintiffs will likely argue, as they did in seeking remand (Dkt. No. 23) ("Remand Mem."), that the Consent Judgment does not cover claims relating to Purdue opioids other than OxyContin. *See* Remand Mem. at 5-7. Yet the focus of the Complaint is Purdue's alleged marketing and promotion of OxyContin and opioids generally. *See* Compl. ¶¶ 85, 93, 203, 208, 213, 240-45, 256-61, 284, 313, 315-19, 324-28, 409; Remand Mem. at 7. The Complaint does not identify purported misrepresentations in branded marketing materials for Purdue's other opioid medications. Purdue's alleged promotion and marketing of opioids generally is undoubtedly "relat[ed] to" its promotion and marketing of OxyContin and therefore covered by the Consent Judgment. Ex. 3 at ¶ 35. Plaintiffs are also wrong that only claims based on violations of ICFA would be barred. *See* Remand Mem. at 6. Subsequent claims are "considered the same cause of action for purposes of *res judicata* if they arise from a single group of operative facts, regardless of whether they assert different theories of relief." *River Park, Inc. v. City of Highland Park*, 703 N.E.2d 883, 893 (Ill. 1998). The Attorney General could have asserted claims under UDTPA and, therefore, that claim is likewise barred.

State. *See, e.g., Time Consumer Marketing, Inc.*, 782 N.E.2d at 767.

The Complaint also provides stark examples of the irreconcilable conflicts that would arise if local State's Attorneys were permitted to file independent actions on behalf of the State circumventing Consent Judgments previously entered by the Illinois Attorney General. For instance, the Consent Judgment *requires* that Purdue "not promote or market OxyContin in a manner that . . . avoids, minimizes, or is inconsistent with individualizing treatment using a plan of pain management, such as outlined by . . . the Federation of State Medical Boards Model Guidelines . . . ." Ex. 3 at ¶ 3. Yet, the Complaint alleges that the Federation of State Medical Boards Model Guidelines are part of a purported fraudulent scheme. Compl. ¶¶ 145-50.

The State is also not a proper party because the Complaint, at base, seeks recovery for expenditures by St. Clair County. *See, e.g.*, Compl. ¶¶ 332-34 ("St. Clair County was damaged directly . . . St Clair County's self -insured health plan made payments for opioids"); *id.* ¶ 347 ("St. Clair County's self-insured health plans only cover the cost of prescription drugs that are medically necessary and dispensed for a FDA-approved purpose"); *id.* ¶ 355 (in 2016, "St. Clair County spent approximately $40,905.11 for 1,492 prescriptions for opioids."). Actions seeking recovery for such proprietary interests, and for recovery on behalf of a subset of the State's population, are not sovereign actions in which the State is a real party in interest. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 601-02 (1982).

Because the St. Clair State's Attorney lacks authority to advance this action on behalf of the People of the State of Illinois, and the Complaint seeks recovery for expenditures by the County, the State is not a proper party and should be dismissed.

**B. The Complaint Falls Well-Short of Rule 9(b) Pleading Requirements.**

The Complaint asserts generalized, sweeping allegations (copied from the previously filed *City of Chicago* complaint) of purported misrepresentations by Purdue without alleging any particularized tie to St. Clair County prescribers or to any alleged improper prescriptions for Purdue medications reimbursed by the County. Despite its 480 paragraphs, the Complaint does not identify *a single* St. Clair County prescriber who allegedly received a misrepresentation from

Purdue, the content of the purported misrepresentation received by that prescriber, when the misrepresentation was received, whether the misrepresentation deceived the prescriber or impacted his or her treatment decision, or any allegedly improper prescription(s) written in St. Clair County due to the alleged misrepresentation. Neither Rule 9(b), nor Illinois law, permits such generalized, untethered "fraud-on-the-market" allegations. *Vicom, Inc. v. Harbridge Merch. Servs., Inc.*, 20 F.3d 771, 777 (7th Cir. 1994); *DiLeo*, 901 F.2d at 627; *Oliveira v. Amoco Oil Co.*, 776 N.E.2d 151, 163-64 (Ill. 2002).

Requiring adherence to Rule 9(b) and the proper identification of the "who, what, when, where, and how" of the alleged fraud in St. Clair County, *see DiLeo*, 901 F.2d at 627, is of heightened importance here given the role of the learned intermediary doctrine and the FDA regulatory framework with respect to these prescription medications.

*First*, Illinois adheres to the learned intermediary doctrine for prescription medicines. *See, e.g.*, *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387 (Ill. 1987). "The doctor, functioning as a learned intermediary between the prescription drug manufacturer and the patient, decides which available drug best fits the patient's needs and chooses which facts from the various warnings should be conveyed to the patient, and the extent of disclosure is a matter of medical judgment." *Id.* at 393. As such, "manufacturers of prescription drugs have a duty to warn prescribing physicians of the drugs' known dangerous propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients." *Id.* at 392. Thus, to advance its claims, the County must plead sufficient facts to demonstrate that a St. Clair County prescriber received a misrepresentation from Purdue, and the misrepresentation resulted in the prescriber writing an improper prescription for a Purdue opioid medication that was then reimbursed by the County. The Complaint does not do so. Instead, it amorphously alleges that "through a sophisticated and highly deceptive and unfair marketing campaign," Compl. ¶ 7, Purdue "change[d] the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain," *id.* ¶ 330. Nowhere in the Complaint do Plaintiffs identify a single St. Clair prescriber who received, let alone was

deceived by, a purported misrepresentation from Purdue. This omission alone is fatal to Plaintiffs' claims.

Proximate causation is "essential in every tort," *Philip Morris*, 817 N.E.2d at 1043, and a required element of each of the claims.[8] Particularity is required to plead that alleged misrepresentations were a cause of alleged injury. For instance, in *Disher v. Tamko Building Products, Inc.*, 2015 WL 4609980, at *5 (S.D. Ill. 2015), the court recognized that allegations regarding misrepresentations on a website and in brochures and advertisements did not satisfy proximate cause where there was no allegation that plaintiff read or viewed the misrepresentations. Where, as here, there are allegations of false or misleading drug marketing, the complaint must include factual detail that "particular doctors with a 'demonstrated connection' to the plaintiff" were misled by the allegedly false marketing. *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 2012 WL 3154957, at *8-9 (N.D. Cal. 2012). The *Bextra* court dismissed Illinois statutory and common law fraud and unjust enrichment claims due to such infirmities. The law instructs that a complaint does not "pass muster under *Iqbal* and *Twombly*" when it fails to allege plausibly "whether any prescriptions were written based on a misunderstanding" resulting from a defendant's purported false statements. *Emp'r Teamsters-Local Nos. 175/505 Health & Welfare Tr. Fund v. Bristol Myers Squibb Co.*, 969 F. Supp. 2d 463, 471-72 (S.D. W. Va. 2013).[9]

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[8] *See People ex rel. Hartigan v. E & E Hauling, Inc.*, 607 N.E.2d 165, 174 (Ill. 1992) (affirming dismissal of ICFA claim where attorney general's complaint failed "to establish . . . a connection" between the misrepresentations and injury and thus failed to "set forth specific facts which show that defendants misrepresented a material fact"); *Philip Morris*, 817 N.E.2d at 1043-48 (affirming judgment on the pleadings of an ICFA public prosecutor claim under the remoteness doctrine for failure to "set forth a direct relationship between the injury asserted and the injurious conduct in th[e] case"); *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 740 (7th Cir. 2014) ("for injunctive relief under [UDTPA], a plaintiff must show that the defendant's conduct will likely cause it to suffer damages in the future."); *City of Chi. v. Purdue Pharma L.P.*, 2015 WL 2208423, at *13-15 (N.D. Ill. May 8, 2015) (dismissing insurance fraud, conspiracy, and unjust enrichment claims, among others, for failure to allege causation).

[9] To the extent the County seeks to hold Purdue liable for illegal drug activity in the County, *(cont'd)*

Rather than allege facts that any St. Clair County prescriber received a misrepresentation that deceived him or her and led to an improper prescription reimbursed by the County, the Complaint references a number of anonymous "Chicago-area prescribers." *See* Compl. ¶ 321. This, however, is insufficient to state a claim on behalf of the County. Not one of the referenced prescribers has any connection to St. Clair County or its residents and therefore cannot form the basis of the County's claims. The Complaint must contain allegations relating to "particular doctors with a '*demonstrated connection*' to the plaintiff." *Bextra*, 2012 WL 3154957, at *8-9 (emphasis added). Even so, the Northern District of Illinois court has twice dismissed fraud-based claims and allegations against Purdue and other defendants under Rule 9(b) for failure to adequately allege causation and injury. *City of Chi.*, 2015 WL 2208423, at *11-12; *City of Chi.*, 211 F. Supp. 3d at 1079-81. The court twice ruled that the plaintiff failed to sufficiently allege a connection between misrepresentations and prescriptions issued by Chicago prescribers, since "the City does not allege . . . the identities of doctors who, as a result of one or more of defendants' alleged misrepresentations, prescribed opioids for chronic pain to a City-insured patient or worker's compensation recipient whose claim for that prescription the City paid, or any other details about such claims." 2015 WL 2208423, at *14. "Under 9(b)'s standard, the City has not alleged enough particularities about injuries to consumers or that those injuries or the monetary damage the City incurred were caused by prescriptions written as a result of defendants' alleged deceptive marketing." 211 F. Supp. 3d at 1076.[10]

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including for illicit opioids and heroin, Comp. ¶¶ 16, 19, or for "opioids manufactured or distributed by other drug makers," *id.* ¶¶ 447, 466, such allegations fail as a matter of settled Illinois law. *See, e.g.*, *City of Chi. v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099 (Ill. 2004); *Young v. Bryco Arms*, 821 N.E.2d 1078, 1091 (Ill. 2004); *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324, 232, 266 (Ill. 1990); *City of Chi. v. Am. Cyanamid Co.*, 823 N.E.2d 126, 135-36 (Ill. App. Ct. 2005).

[10] The court upheld only two claims alleging violations of the Chicago Municipal Code, which does not apply here. *See City of Chi.*, 211 F. Supp. 3d at 1074, 1076. The City of Chicago has since filed a Third Amended Complaint, and defendants have again moved to dismiss all but the two Municipal Code claims for, among other reasons, failure to adequately allege causation.

*(cont'd)*

The Complaint's pleading deficiencies are further compounded by the failure to allege that the County's prescription benefits managers—OptumRx and ClaimsOne—were misled in making payment decisions. *See* Comp. ¶¶ 344, 358. While the County grounds its claims in the assertion that "use of opioids to treat chronic pain is not medically necessary or reasonably required in that their risks do not materially exceed their benefits," *id.* ¶ 364, the Complaint nowhere alleges that the actual decision-makers responsible for determining whether such treatments are "medically necessary"—the prescription benefits managers—received any alleged misrepresentation or were deceived by Purdue. The County's claims are thus independently subject to dismissal for this additional reason. *See S. Ill. Laborers' & Emp'rs Health & Welfare Fund v. Pfizer Inc.*, 2009 WL 3151807, at *5-6 (S.D.N.Y. 2009) (dismissing claims where plaintiffs failed to tie alleged misrepresentations to "pharmacy benefit decision makers"); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 525 (D.N.J. 2011) (same).

Not only does the Complaint fail to identify any particular instance in which a St. Clair prescriber or a County's prescription benefits manager received a misrepresentation from Purdue that resulted in an improper prescription for a Purdue opioid medication that was reimbursed by the County, the Complaint also alleges injuries that fail, as a matter of law, pursuant to the remoteness doctrine. For instance, the Complaint alleges that "Defendants' deceptive marketing" caused "County patients" to incur costs and injuries, "including doctors' visits, toxicology screens, hospitalization for overdoses, treatment and other adverse effects of opioids, and long-term disability," which in turn "caused St. Clair County[] to incur additional costs." *Id.* ¶ 354. Such allegations are far too remote under Illinois law. They are legally insufficient to show that Defendants' "conduct is so closely tied to the plaintiff's injury that [they] should be held legally responsible for it." *Beretta U.S.A. Corp.*, 821 N.E.2d at 1127.

In a similar example, Illinois courts affirmed dismissal of a county's attempt to recover

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*City of Chi.*, No. 14-4361, Dkt. Nos. 478, 492-93, 513, 517. Those motions remain pending.

damages from tobacco manufacturers for the cost of health care for tobacco consumers in the county. *Philip Morris*, 817 N.E.2d at 1041. The plaintiffs alleged that the defendants had "conspired to suppress information about the adverse and addictive qualities of nicotine" and "[a] direct result of the defendants' actions was . . . to contribute to Cook County's overall increased healthcare costs." *Id.* at 1042-43. But because "[p]roof of a causal relationship between a defendant's action and a plaintiff's injury is essential in every tort," *id.* at 1043, the Appellate Court held that the county's claims were "correctly dismissed on the basis of the remoteness doctrine," given "the derivative nature of the injuries alleged." *Id.* at 1048. Here, as in *County of Cook*, sweeping claims for indirect healthcare costs such as general "doctors' visits" have no "reasonable connection" to the Defendants' alleged conduct. *Id.* at 1043. Any injury to Plaintiff "results only indirectly: if a [] consumer [of the product] needs treatment and if" those costs allegedly get passed on to the County. *Id.* at 1048. Thus, any damage the County incurred was indirect and too remote to have a "reasonable connection" or be "closely tied" to the Defendants' alleged conduct.

*Second*, identifying the specific alleged misrepresentations to St. Clair County prescribers is of heightened importance given legal principles relating to the primary role of FDA in the regulation of Purdue prescription opioids. Statements consistent with FDA-authorized labeling, based on information previously submitted to FDA, cannot be the basis of misrepresentation claims under state law. *Bober ex rel. Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 941 (7th Cir. 2001); *Price v. Philip Morris, Inc.*, 848 N.E.2d 1, 48 (Ill. 2005). Thus, statements that "generally comport with [a drug's] approved label" are "not misleading as a matter of law" and cannot form the basis of a fraud-based claim. *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1235 (S.D. Fla. 2007); *see also, e.g.*, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34 (1st Cir. 2015) (addressing preemption).[11]

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[11] The UDTPA and insurance fraud claims also require allegations of deceptive conduct. *See* 815 ILCS 510/2(a); 720 ILCS 5/17-10.5.

The Complaint's central allegation is that Purdue falsely represented that opioid products are safe and effective for long-term treatment of chronic pain. *See, e.g.*, Compl. ¶¶ 9, 13, 154. But FDA approved Purdue's products as safe and effective for that very use. *See* OxyContin Label at 1 ("OXYCONTIN is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, *long-term* opioid treatment and for which alternative treatment options are inadequate." (emphasis added)), attached hereto as Ex. 4.[12] The Complaint also makes allegations that Purdue deceptively promoted OxyContin for 12-hour dosing. Compl. ¶ 244 ("Purdue advertisements also emphasized 'Q12h' (meaning twice-daily) dosing"); *id.* (advertisements in medical journals in 2005 and 2006 "featur[ed] an OxyContin logo with two pill cups, reinforcing the twice-a-day message"). Yet the FDA-approved label for OxyContin *instructs* users to dose every 12 hours. Ex. 4 at § 2.1 ("OXYCONTIN is administered orally every 12 hours"). Because these statements comport with FDA-approved labels, they cannot form the basis of a fraud-based claim, including ICFA and UDTPA claims. *Bober*, 246 F.3d at 940-43.[13]

The allegations that Purdue "omitted" from their marketing known, serious risks of opioids, such as addiction and abuse, are similarly defective. *See, e.g.*, Compl. ¶ 197, 201, 207, 208(v), 210-11, 227(j), 236, 239(m), 318, 321(c). As the Complaint acknowledges, "[t]he labels for scheduled opioid drugs carry black box warnings of potential addiction," Compl. ¶ 45, and

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[12] *See also Extended-Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS)* at 15 (stating that ER/LA opioids, specifically listing Purdue products, are "[n]ot for mild or pain not expected to persist for an extended duration"), attached hereto as Ex. 5. Purdue's product label, which is referred to in the Complaint, *see, e.g.*, Compl. ¶¶ 22, 29, 42, 45, 52, 54, 192, and is central to the claims in the Complaint, may be considered by the Court in resolving this motion to dismiss. *See Tierney*, 304 F.3d at 738. The Court may also take judicial notice of the REMS, which is a matter of public record. *See Ennega v. Starns*, 677 F.3d 766, 773 (7th Cir. 2012); *Ibarrola v. Kind, LLC*, 2014 WL 3509790, at *2 (N.D. Ill. July 14, 2014) (taking judicial notice of FDA draft guidance and FDA notice).

[13] The Consent Judgment prohibits Purdue from promoting in any way inconsistent with the FDA-approved label. Yet Plaintiffs are now suing Purdue in part for complying with the requirements of the Consent Judgment the Illinois Attorney General obtained.

the risks of "dependence, tolerance, and addiction" are "fully disclosed in the labels for each of Defendants' opioids," *id.* ¶ 52. For instance, the FDA-approved label for OxyContin includes a box warning stating:

> **WARNING: ADDICTION, ABUSE AND MISUSE . . . .**
>
> ***See full prescribing information for complete boxed warning.***
>
> **OXYCONTIN exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly these behaviors and conditions. (5.1)**

Ex. 4 at 1.[14] Thus the allegations that Purdue deceptively omitted such risks necessarily fails when considered within the context of the totality of the information available to the prescriber. *See Bober*, 246 F.3d at 938-39; *Kirk*, 513 N.E.2d at 392-93; *see also Davis v. G.N. Mortg. Corp.*, 396 F.3d 869, 884 (7th Cir. 2005); *Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014) ("physician-prescribers are presumed to have knowledge of a drug label's contents.").

In sum, it is necessary for the County to allege with particularity which St. Clair prescriber received a purported misrepresentation ("who"), the content of the misrepresentation ("what"), when and where the prescriber received the misrepresentation ("when, where"), and how the misrepresentation allegedly deceived the prescriber and resulted in an improper prescription reimbursed by the County ("how"). *See DiLeo*, 901 F.2d at 627. In contrast, the County has failed to identify a *single* instance of a misrepresentation made to a St. Clair prescriber which failed to comport with FDA-approved labeling, misled the prescriber, and resulted in an improper prescription reimbursed by the County.

**C. The Complaint Fails to Allege Facts Demonstrating That Purdue Controlled**

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[14] The Complaint also acknowledges that "FDA has required extended release and long-acting opioids to adopt 'Risk Evaluation Mitigation Strateg[ies]' [("REMS")] on the basis that they present 'a serious public health crisis of addiction, overdose, and death.'" Compl. ¶ 54. The REMS, which includes prescriber training, is attached as Ex. 5.

**the Content of Third-Party Publications.**

Throughout the Complaint, the County references alleged misrepresentations that appear in publications written and published by third parties. Yet Plaintiffs fail to allege any facts, let alone with particularity, to establish that Purdue exercised the requisite control over the content of such third-party statements, as necessary to state a claim.

Allegations of purported misrepresentations in third-party unbranded marketing materials cannot be attributed to Purdue absent bona fide allegations that the third-party materials were prepared either at the direction of Purdue or by its agents. As the court in *City of Chicago* held, these claims fail absent allegations that Purdue exercised "editorial control" over the purported misrepresentations, despite having "allegedly sponsored or funded" the same third-party publications. 2015 WL 2208423, at *11-12. The Illinois Supreme Court has likewise affirmed the dismissal of common law fraud claims where the plaintiffs failed to allege that the manufacturer "expressly gave authority to the [third party] to bind [manufacturer] to statements [at issue]" or that the third party had "implied authority from [manufacturer] sufficient to impose liability [on the manufacturer] for [its] fraudulent statements." *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584, 592-94 (Ill. 1996).

The Complaint does not allege an agency relationship between Purdue and the named third parties or any facts showing that Purdue had editorial control over the allegedly misleading content in the third-party publications. Instead, the Complaint relies on conclusory allegations that Purdue "funded," "sponsored," or otherwise controlled third-parties and their publications. For example, the Complaint alleges that Purdue, and other "drug manufacturers" "backed," "sponsored," and "financed the distribution" of the Federation of State Medical Boards' ("FSMB") *Responsible Opioid Prescribing*. *See* Compl. ¶¶ 148, 303-04. Yet the Complaint does not allege that Purdue exercised any control over the FSMB or the content of the publication. This is not surprising. FSMB is a "trade organization representing the various state medical boards in the United States." *Id.* ¶ 145. The allegations as to the other third-party publications are similarly deficient. *See id.* ¶¶ 227(e), 305, 307 (funding to American Geriatrics

Society for CME and distribution of publications); *id.* ¶¶ 208(t)-(v), 227(b)-(c), 287, 292, 294, 300 ("sponsored" *Policymaker's Guide*, *Treatment Options* and *Exit Wounds*); *id.* ¶¶ 235(d), 239(o), 308-10, 311 ("sponsored" CMEs); *id.* ¶¶ 227(d), 313 ("funded" studies and articles).

Because the Complaint fails to adequately plead that Purdue exercised the requisite control over the purported misrepresentations in the third-party publications, the claims based on these publications should be dismissed.

**D. Each of the Counts Suffers From Numerous Additional Deficiencies and Fails to State a Claim as a Matter of Law**

**1. The Illinois Consumer Fraud Act Claim (Count 1) Must Be Dismissed.**

(a) St. Clair County Lacks Standing to Bring a Claim Under ICFA.

As noted above, the State of Illinois is not a proper party to this action and must be dismissed. With respect to St. Clair County, Illinois law establishes that counties and other political subdivisions do not have statutory standing to pursue claims under ICFA. By its terms, ICFA defines a "person" capable of bringing suit as "any natural person or his legal representative, partnership, corporation (domestic and foreign), company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof." 815 ILCS 505/1(c). "Under the ICFA, a municipality is not a person capable of bringing suit." *City of Fairview Heights v. Orbitz, Inc.*, 2006 WL 6319817, at *6 (S.D. Ill. July 12, 2006) (dismissing ICFA claim); *see Bd. of Educ. v. A, C & S, Inc.*, 546 N.E.2d 580, 599 (Ill. 1989).

As a political subdivision, the County also lacks parens patriae authority to bring this action on behalf of its residents. "[T]he doctrine of parens patriae cannot be asserted by political subdivisions such as cities and counties." *Village of Niles v. U.S. Postal Serv.*, 1985 WL 2900, at *5 n.3 (N.D. Ill. Sept. 30, 1985).

(b) Purdue Cannot be Held Liable Under ICFA for Statements Made in Unbranded Publications.

Nearly all of the allegations relate to unbranded publications—including scientific

articles, prescribing guidelines, and CMEs—about opioids generally and pain management, which cannot support a claim under ICFA because they do not constitute advertising or offers for sale. ICFA proscribes "unfair or deceptive acts or practices . . . in the conduct of any trade or commerce." 815 ILCS 505/2. ICFA further defines "trade or commerce" as "advertising, offering for sale, sale, or distribution" and "advertisements" as offers to sell or attempts to induce a sale." *Id.* 505/1(a), (f). The Complaint acknowledges that the unbranded materials are not tied to any specific opioid medication, *see* Compl. ¶ 113, and does not allege that they were offers to sell or attempts to induce a sale. The County's claim that this material violated ICFA should thus be dismissed.

**2. The Uniform Deceptive Trade Practices Act Claim (Count 2) Must Be Dismissed.**

Plaintiffs, copying from the *City of Chicago* complaint, allege that Purdue "engag[ed] in unfair acts or practices to promote the sale and use of opioids to treat chronic pain" in violation of UDTPA.[15] Compl. ¶ 451, *see also id.* ¶¶ 452-55. Yet the Northern District of Illinois court twice dismissed the same unfair practices allegations, finding that the complaint failed to allege any "unfair" conduct under the three factors in *Robinson v. Toyota Motor Credit Corp.*, 775 N.E.2d 951, 960 (Ill. 2002). *See City of Chi.*, 211 F. Supp. 3d at 1074-75. So, too, here.

*First*, the Complaint identifies no "public policy" the conduct supposedly "offend[ed]." *Robinson*, 775 N.E.2d at 961. While the Complaint cites 745 ILCS 35/2, Compl. ¶ 454 n.103, that statute's stated policy—"to promote and encourage use of [an] intervention process to help initiate" addiction treatment—has "no bearing on" the claims alleged here. *City of Chi.*, 211 F. Supp. 3d at 1075. Also insufficient is the Complaint's vague and conclusory allegation that Defendants "worked to undermine public policy, enshrined by" unspecified laws "aimed at

[15] Notably, unfair acts or practices are a violation of ICFA, not a violation of UDTPA, which is focused only on *deceptive* trade practices. *Compare* 815 ILCS 510/2 (UDTPA covers "deceptive trade practice") *with* 815 ILCS 505/2 (ICFA covers "unfair or deceptive acts or practices").

ensuring honest marketing and safe and appropriate use of pharmaceutical drugs." Compl. ¶ 454. The law instructs that a "bare assertion of unfairness without describing in what manner the [conduct] . . . violate[s] public policy or [is] oppressive is insufficient." *Robinson*, 775 N.E.2d at 963. As the court ruled in *City of Chicago*, 211 F. Supp. 3d at 1075, "[w]ithout more than an assertion that these federal statutes reflect the public policy the City infers, the Court is hesitant to affirm that such a public policy exists or is one the legislature intended."

*Second*, the Complaint fails to allege facts showing that Purdue's conduct was "immoral, unethical, oppressive, or unscrupulous." *Robinson*, 775 N.E.2d at 961. The Complaint asserts Purdue's alleged conduct "was oppressive to both patients and prescribers" by "co-opt[ing] the sources reasonable physicians relied upon" and "target[ing] non-specialist physicians and non-physician prescribers." Compl. ¶ 455. But to state an unfairness claim, conduct must be "so oppressive as to leave the consumer with little alternative except to submit to it." *Robinson*, 775 N.E.2d at 961. Given the availability of treatment options and the Complaint's concession that opioid risks are disclosed in product labeling, Compl. ¶ 52, the County cannot plausibly claim that the alleged conduct left prescribers with "little alternative" but to embrace opioids. "[P]laintiff has not alleged that no other choice existed." *City of Chi.*, 211 F. Supp. 3d at 1075.

*Third*, the Complaint fails to plead "substantial injury to consumers," *Robinson*, 775 N.E.2d at 961; *see also City of Chi.*, 211 F. Supp. 3d at 1075-76, and instead alleges injuries to the County itself.

The UDTPA claim also fails because the Complaint does not allege facts showing that Plaintiffs are "likely to be damaged in the future by [Purdue's] conduct." *Glazewski v. Coronet Ins. Co.*, 483 N.E.2d 1263, 1267 (Ill. 1985). "To be eligible for injunctive relief under [UDTPA], a plaintiff must show that the defendant's conduct will likely cause it to suffer damages in the future." *Camasta*, 761 F.3d at 740. Yet the UDTPA count alleges only that Plaintiffs were damaged in the past. *See* Compl. ¶ 458. "However, '[p]ast exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief." *Camasta*, 761 F.3d at 740 (alteration in original) (quoting *O'Shea v. Littleton*, 414 U.S. 488, 495 (1974)).

**3. The Civil Conspiracy Claim (Count 3) Must Be Dismissed.**

Failure to adequately plead an underlying claim defeats the County's civil conspiracy claim. *See Ablan v. Bank of Am. Corp.*, 665 Fed. App'x 544, 545 (7th Cir. 2016) ("To succeed on a civil conspiracy claim [under Illinois law], a plaintiff must establish an underlying tort."); *Indeck N. Am. Power Fund, L.P. v. Norweb P.L.C.*, 735 N.E.2d 649, 662 (Ill. App. Ct. 2000).

The Complaint also fails to allege an agreement to commit an unlawful act, let alone with the particularity required by Rule 9(b). *See Borsellino*, 477 F.3d at 507; *Frederking v. Zurich Am. Ins. Co.*, 2016 WL 3965896, at *2-3 (S.D. Ill. July 25, 2016). A conspiracy claim must allege sufficient facts from which a court may infer the existence of a conspiratorial agreement between the parties to violate the law. *Bean v. Pub. Defender's Office of St. Clair Cty., Ill.*, 2014 WL 3835063, at *3 (S.D. Ill. July 25, 2014); *United States ex rel. Lisitza v. Par Pharm. Cos.*, 2013 WL 870623, at *7 (N.D. Ill. Mar. 7, 2013). A "conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality." *Twombly*, 550 U.S. at 557. Because the Complaint lacks non-conclusory allegations that there was a conspiratorial, unlawful agreement between Purdue and any alleged third-party, the claim fails as a matter of law. *See Borsellino*, 477 F.3d at 509.

**4. The Insurance Fraud Claim (Count 4) Must Be Dismissed.**

The County's insurance fraud count fails to plead a requisite false claim.[16] To do so, the County must link "specific allegations of deceit . . . to [a] claim for payment." *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 378 (7th Cir. 2003). It has not. *First*, rather than identify specific false claims, the Complaint asserts that *all* reimbursement claims for opioids prescribed to treat chronic non-cancer pain are false. Compl. ¶ 353. To begin, such a claim is untenable as a matter of law in light of FDA's express determination that Purdue opioid

[16] 720 ILCS 5/17-10.5(a)(1) prohibits "the making of a false claim or [] causing a false claim to be made on any policy of insurance . . . [or] to a self-insured entity." "Without an underlying false claim, a claim for insurance fraud premised on a false claim fails." *City of Chi.*, 211 F. Supp. 3d at 1083.

medications are appropriately indicated for the treatment of chronic pain. *See, e.g.*, *In re Celexa*, 779 F.3d 34. Moreover, the Seventh Circuit has repeatedly rejected such a mode of pleading, holding allegations that fail to identify specific false claims insufficient as a matter of law. *See United States ex rel. Crews v. NCS Healthcare of Ill, Inc.*, 460 F.3d 853, 858 (7th Cir. 2006); *United States ex rel. Grenadyor v. Ukranian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1107 (7th Cir. 2014). The County must identify specific false claims for payment. *See Garst*, 328 F.3d at 376; *United States ex rel. Turner v. Michaelis Jackson & Assocs.*, 2007 WL 496384, at * 4 (S.D. Ill. Feb. 13, 2007); *City of Chi.*, 211 F. Supp. 3d at 1081, 1083 (dismissing insurance fraud counts).

*Second*, the Complaint impermissibly relies on "implied certification." Compl. ¶¶ 347-50, 362-63. As directed by the Supreme Court in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), implied false certification can be a basis for liability only "where two conditions are satisfied: first, the claim does not merely request payment, but also makes *specific representations* about the goods or services provided; and second, the defendant's failure to disclose *noncompliance* with *material* statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001 (emphasis added). The Complaint does not satisfy either requirement. It fails to identify *any* "specific representations" made to the County, nor does it plead any fact that would establish that any prescriptions paid for by the County were not medically necessary or reasonably required. Rather, "a drug prescribed for its on-label use—by definition—means that the prescription is medically reasonable for its intended purpose by virtue of the FDA approval process." *In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.*, 123 F. Supp. 3d 584, 604 (D.N.J. 2015).

Moreover, the County admits it continues to pay for opioids prescribed for chronic pain. Compl. ¶ 465. This admission establishes that the alleged misrepresentations were *not* material to its payment decisions as a matter of law. *Universal Health Servs.*, 136 S. Ct. at 2003-04. Where, as here, the plaintiff "is still paying for claims based on defendants' alleged misrepresentations[,] . . . that plaintiff has not sufficiently alleged that defendants caused misrepresentations that were material as defined in *Universal Health*." *City of Chi.*, 211 F. Supp.

3d at 1079.

*Third*, from the premise that "Defendants' deceptive marketing rendered opioids misbranded as prescribed for chronic pain," the Complaint asserts that "Defendants' opioids were not FDA-approved, within the meaning of the St. Clair County's health plans, for the long-term treatment of chronic pain," and thus ineligible for reimbursement. Compl. ¶ 352. This theory fails as a matter of law. While the Complaint invokes 21 U.S.C. § 352, the Federal Food, Drug, and Cosmetic Act ("FDCA") vests exclusive enforcement authority of these provisions in the federal government, rendering the County's attempt to declare Purdue's drugs misbranded preempted under the Supremacy Clause. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). "Congress intended that the [FDCA] be enforced exclusively by the Federal Government." *Id.* (citing 21 U.S.C. § 337(a)). Thus, "such a claim would be impliedly preempted under *Buckman*." *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010).

**5. The Unjust Enrichment Claim (Count 5) Must Be Dismissed.**

The County's unjust enrichment claim is derivative of the other claims and fails for the same reasons. "[I]f an unjust enrichment claim rests on the same improper conduct alleged in another claim, then . . . unjust enrichment will stand or fall with the related claim." *Cleary v. Philip Morris Inc.*, 656 F.3d 511, 517 (7th Cir. 2011); *see City of Chi.*, 211 F. Supp. 3d at 1084. This claim also fails because the Complaint does not allege facts showing that (1) Purdue "has unjustly retained a benefit to the [County's] detriment," *HPI Healthcare Servs., Inc. v. Mt. Vernon Hosp.*, 545 N.E.2d 672, 679 (Ill. 1989), or (2) the County has no adequate remedy at law, *Season Comfort Corp. v. Ben A. Borenstein Co.*, 655 N.E.2d 1065, 1071 (Ill. App. Ct. 1995). As discussed above, the Complaint does not adequately allege that the County was harmed or that Purdue caused any such harm. And nothing suggests that the County's statutory or other common law remedies would be inadequate.

## IV. CONCLUSION

For the foregoing reasons, Purdue respectfully request the Court dismiss all claims against Purdue.

Dated: August 16, 2017

By: /s/ Troy A. Bozarth

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**CERTIFICATE OF SERVICE**

I certify that on August 16, 2017, I electronically filed a true and correct copy of the foregoing Memorandum of Law in Support of Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company Inc.'s Motion to Dismiss for Failure to State a Claim with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing upon counsel of record of all parties.

/s/ Troy A. Bozarth
Troy A. Bozarth